

# Review Programme: ECHA takes action

Biocides Day

29 October 2019

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European Chemicals Agency



# Overview

- Status and trend
- What has been done?
- How to go further?

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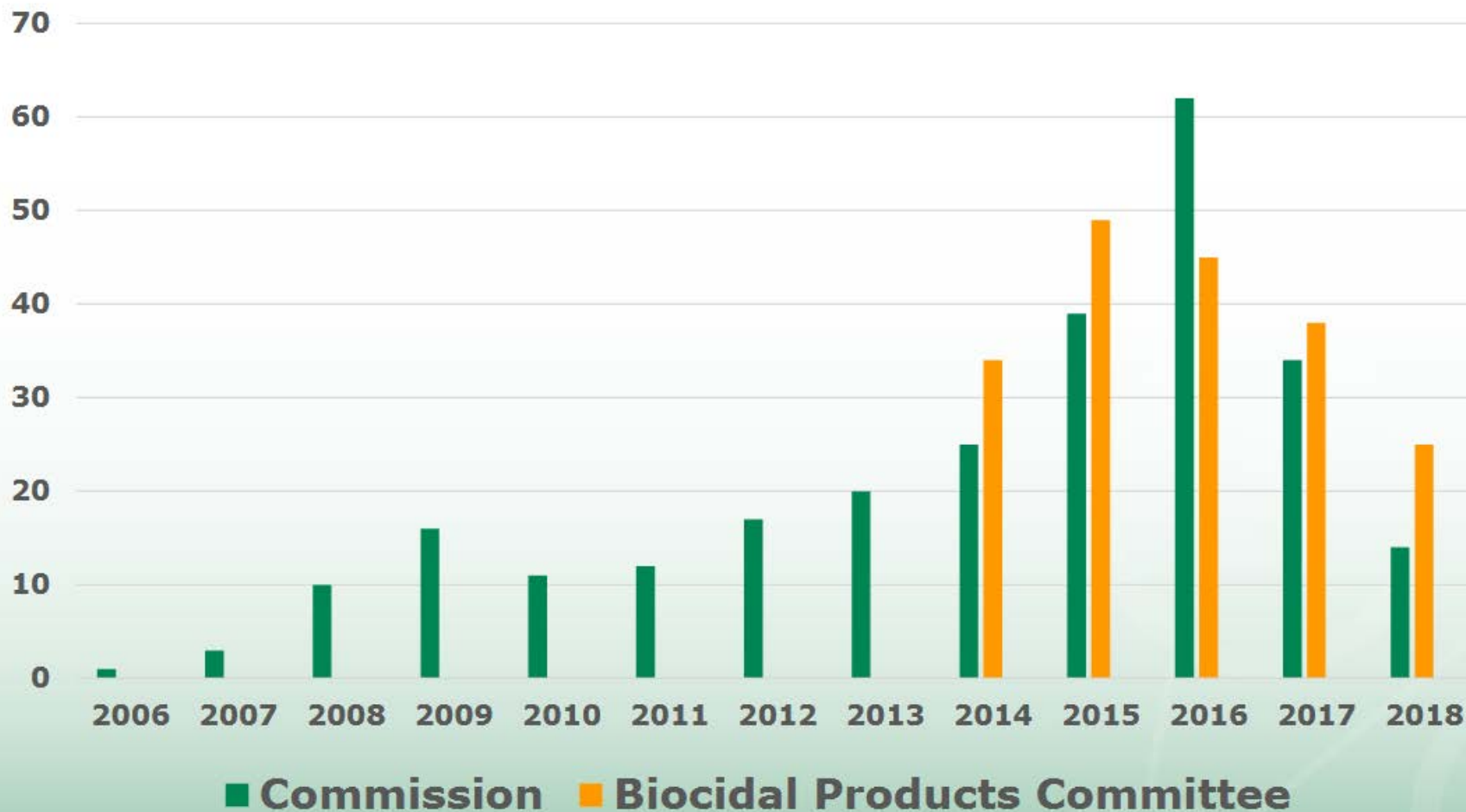


## Status and perspective

- 1/3 finalised after 15 years
- 5 years remaining
  - would require more than 80 opinions per year

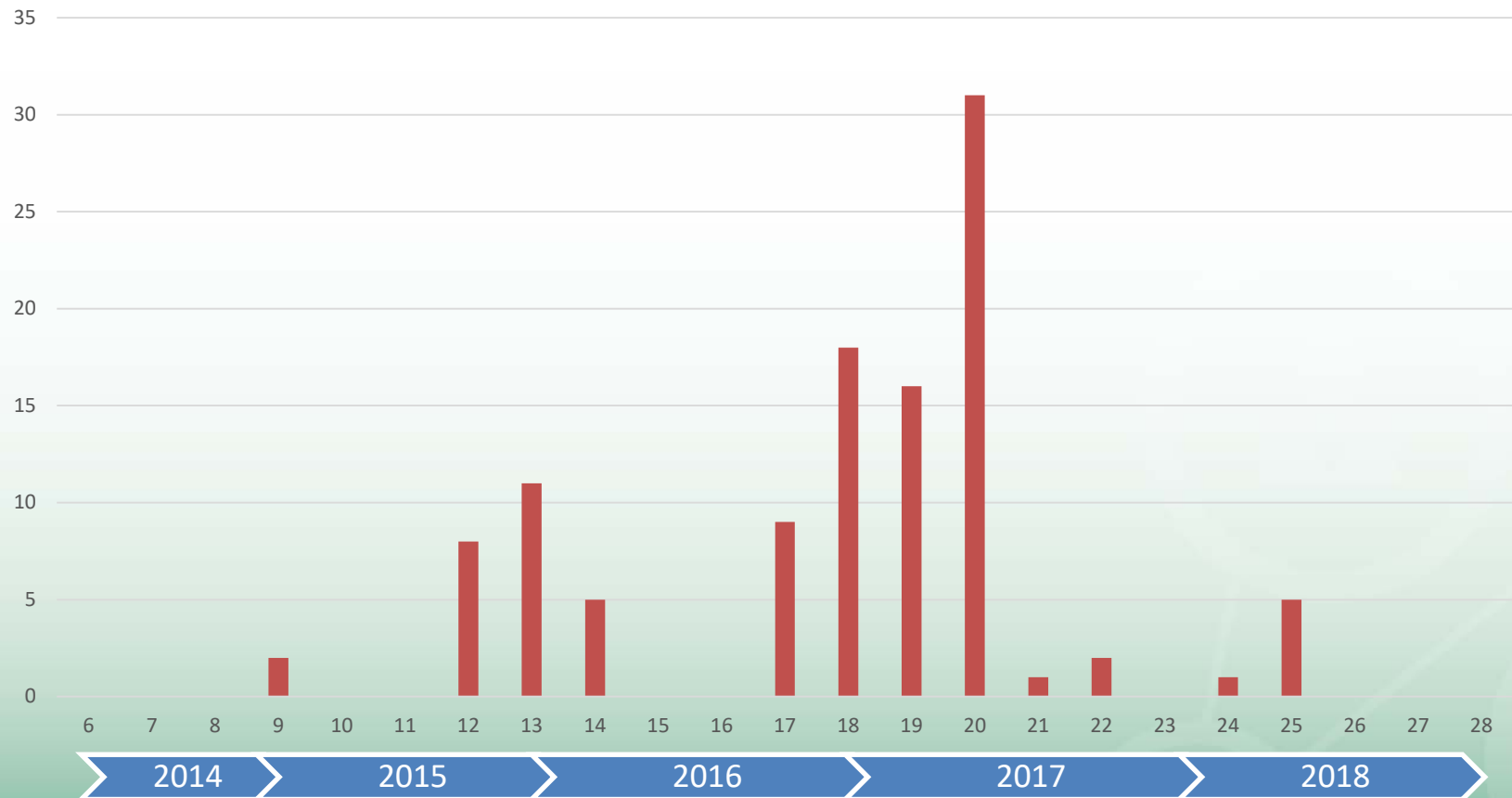


## Trend – active substance approvals



# Trend – draft CA reports (CARs)

Submissions of 1st draft CARs (Process Flows 6 – 28)



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# Survey « Grip on the Review Programme »

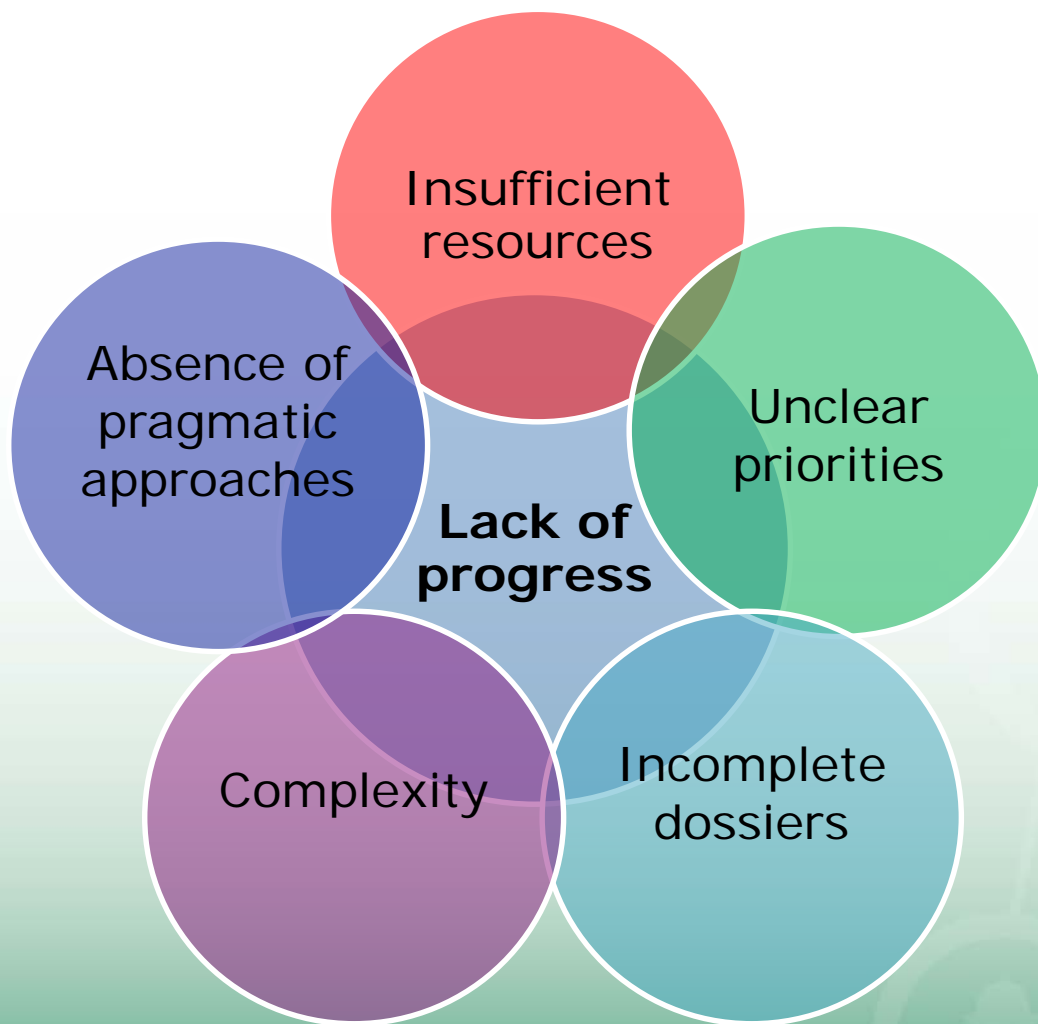
- Objectives:
  - Know the status of each Review Programme dossier under evaluation
  - Identify causes preventing progress
  - Develop cooperation during the evaluation phase
- April–September 2018
- Main outcomes:
  - Identification of the most important issues
  - Identification of common issues



# Active substance workshop 2019

- Objectives:
  - Identify causes for the slow down of the Review Programme
  - Find solutions and improve the process
- Important participation
- Identification of main causes and pragmatic solutions
- Start of concerted action

# Causes for lack of progresses



# Prioritisation of dossiers and support

Issues to address:

Insufficient  
resources in MSs

Unclear priorities

## Actions:

1. Clarify the priorities: backlog + Review programme priority lists
2. Direct support by ECHA
  - e.g. Diamine PT8: exposure and risk assessment

# Support for ED assessment

Issue to address:

Insufficient  
resources in MSs

## Actions:

1. Practical recommendations to support applicants and eCAs in preparing the ED assessment.  
Finalisation foreseen Q4 2019 – Q1 2020
2. ED expert group: advice by the expert group
  - to date 12 dossiers (16 substances) discussed
3. Direct support by ECHA for ED assessment
  - support provided for 12 dossiers (8 MS)

# Relationship with applicants

Issue to address:

Incomplete dossiers

## **Actions:**

1. Procedural guidance to request additional information and dealing with applicant not submitting the requested information
2. Related letter templates

# Peer review streamlining

Issue to address:

Complexity

## Actions:

1. New RCOM template: includes indication of the impact of the comment and a justification
2. Early working groups: document listing items always to be discussed at early working groups
3. Ad hoc follow up: document clarifying the triggering
4. Reopening agreements: rules for reopening TM/WG agreements

# Information clearer and easier to find

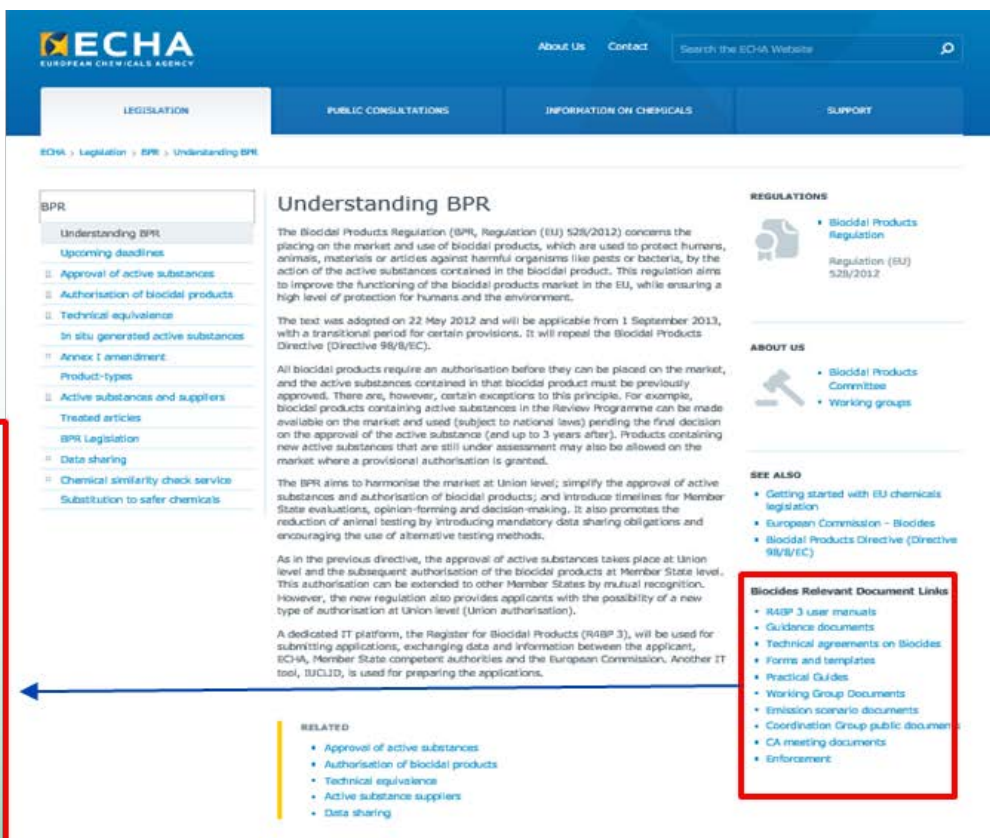
Issues to address:

Complexity

## Actions:

1. Links to key documents on ECHA's website
2. Mapping and clarification of quasi guidance documents (ongoing)
3. Improving the format of TAB (ongoing)

# Improving the access to information



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EUROPEAN CHEMICALS AGENCY

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LEGISLATION PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

ECHA > Legislation > BPR > Understanding BPR

**BPR**

- Understanding BPR
- Upcoming deadlines
- Approval of active substances
- Authorisation of biocidal products
- Technical equivalence
- In situ generated active substances
- Annex I amendment
- Product-types
- Active substances and suppliers
- Treated articles
- BPR Legislation
- Data sharing
- Chemical similarity check service
- Substitution to safer chemicals

## Understanding BPR

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

The text was adopted on 22 May 2012 and will be applicable from 1 September 2013, with a transitional period for certain provisions. It will repeal the Biocidal Products Directive (Directive 98/5/EC).

All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved. There are, however, certain exceptions to this principle. For example, biocidal products containing active substances in the Review Programme can be made available on the market and used (subject to national laws) pending the final decision on the approval of the active substance (and up to 3 years after). Products containing new active substances that are still under assessment may also be allowed on the market where a provisional authorisation is granted.

The BPR aims to harmonise the market at Union level; simplify the approval of active substances and authorisation of biocidal products; and introduce timelines for Member State evaluations, opinion-forming and decision-making. It also promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods.

As in the previous directive, the approval of active substances takes place at Union level and the subsequent authorisation of the biocidal products at Member State level. This authorisation can be extended to other Member States by mutual recognition. However, the new regulation also provides applicants with the possibility of a new type of authorisation at Union level (Union authorisation).

A dedicated IT platform, the Register for Biocidal Products (R4BP 3), will be used for submitting applications, exchanging data and information between the applicant, ECHA, Member State competent authorities and the European Commission. Another IT tool, IUCLID, is used for preparing the applications.

**REGULATIONS**

- Biocidal Products Regulation Regulation (EU) 528/2012

**ABOUT US**

- Biocidal Products Committee
- Working groups

**SEE ALSO**

- Getting started with EU chemicals legislation
- European Commission – Biocides
- Biocidal Products Directive (Directive 98/5/EC)

**Biocides Relevant Document Links**

- R4BP 3 user manuals
- Guidance documents
- Technical agreements on Biocides
- Forms and templates
- Practical Guides
- Working Group Documents
- Emission scenario documents
- Coordination Group public documents
- CA meeting documents
- Enforcement

**RELATED**

- Approval of active substances
- Authorisation of biocidal products
- Technical equivalence
- Active substance suppliers
- Data sharing

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## Interface CLP – BPR

Issues to address:

Complexity

Insufficient  
resources in MSs

### Actions:

1. Improved CAR–CLH template
2. Revitalise joint MSCAs task force CLH–biocides

# Harmonised assessment of confidentiality claims

Issues to address:

Complexity

## Actions:

- Recommendations for assessing confidentiality claims for CARs (under preparation), finalisation foreseen Q4 2019 – Q1 2020

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## Making the approach sustainable

- Need for coordinated action
- Need for MSCAs commitment and cooperation
- ECHA's resources alone are not sufficient
- Policy and even legislation may need to be re-discussed

**→ Action plan for CA meeting agreement**

## Addressing resource needs

- Support and coordination by ECHA
- Support by other MSCAs
- Support by external experts
- MSCAs resources building
- Grouping active substances to reduce overall resource needs

# Improving effectiveness and efficiency

- Harmonise assessments
- Streamline peer review
- Limit revision of the assessment to formal review (Article 15) and renewal
- Optimise the ED assessment strategy for substances already meeting exclusion criteria
- Improve CLP–BPR interface

# Thank you

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